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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,566	11/14/2003	Yong-Qian Wu	3004-A	8262

29035 7590 05/16/2005

GUILFORD PHARMACEUTICALS, INC.
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BALTIMORE, MD 21224

EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,566

Applicant(s)

WU ET AL.

Examiner

Rita J. Desai

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 39-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1625

DETAILED ACTION***Election/Restrictions***

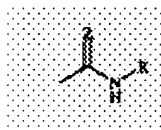
Applicants elected group V of the restriction without traverse.

V. Claims 29-38 in part, drawn to method of treating a neurological disease, classified in various classes and subclasses. A further election of a single disclosed species is required. May be subject to restriction.

Applicants elected species of compound 42 on page 24 of the specification.

The group is being further restricted to

Claims 29-38 in part drawn to a method of treating neurological disease using compound of formula I wherein X and Y are the same as given by the first definition ($---C=Z-NH-R$),



V is an alkyloxy substituted by Q wherein Q is mono, bi or tricyclic carbocyclic ring, and R is also a Q which is a mono, bi or tricyclic carbocyclic ring.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites method of “using” but does not clearly state “to treat ...”

Art Unit: 1625

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for neurological condition, Parkinson's disease, does not reasonably provide enablement for any and all the listed diseases, which includes metabolic disorders, nutritionally related disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) The breadth of the claims: The instant claims encompass many compounds ranging from an aromatic carbocyclic moiety with numerous groups hanging from them. These compounds cover a very wide range of compounds.

2) The nature of the invention: The invention is to treat neurological diseases

3) The state of the prior art: Drugs do not have an umbrella efficacy to treat numerous diseases. Even a difference of a Hydrogen group instead of a methyl group changes the properties of the compounds. E.g. theophylline and caffeine, one of them is a broncho dilator.

4) The level of one of ordinary skill: The ordinary artisan is highly skilled.

5) The level of predictability in the art: The level of unpredictability in the art is very high since drugs act on receptor sites and receptors at different places are different. Receptors in the spinal cord are different from the receptors in the brain or peripheral nervous system.

Art Unit: 1625

6) The amount of direction provided by the inventor: The inventor provides very little direction in the instant specification. Only treating Parkinson's data is provided with compound number 42 and compound 44.

Table B has IC50 data for other compounds but it ranges from n.d. to 15,200, which really does not provide any guidance that these compounds would have any activity or not.

7) The existence of working examples: There is a wide variety of Neurological disorders and drugs do not have an umbrella efficacy of treating all the various disorders. Especially since the compounds have a large scope and also since there are a variety of diseases.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: Since there is no sufficient data provided, the amount of experimentation is very high and burdensome. Also, just treating Parkinson's do not represent the fullest extent of the instant claim 29-38.

Taking the above eight factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instantly claimed invention.

Conclusion

The claims 28-38 are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
May 11, 2005

RJ Desai
5/12/05